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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,726	10/22/2003	Paul R. Schmidt	1443.063US1	6851
7590 11/01/2005			EXAMINER	
Schwegman, Lundberg, Woessner & Kluth, P.A.			FIDEI, DAVID	
P.O. Box 2938			ART UNIT	
Minneapolis, MN 55402			PAPER NUMBER	
			3728	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,726

Applicant(s)

SCHMIDT ET AL.

Examiner

David T. Fidei

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 18-30 and 36-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 31-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/03 & 10/4/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17, 31-35, drawn to a package, classified in class 206.
 - II. Claims 18-30 and 36-39, drawn to a method, classified in class 53.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as broadly claimed can be practiced by a different method such as one that punctures a sealing membrane.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Mr. Andrew Peret on October 26, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-17 and 31-35. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-30 and 36-39 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

3. The information disclosure statement filed November 17, 2003 fails to comply with 37 CFR 1.98(a)(2), which required a legible copy of each patent document submitted at that time. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Riese (Patent no. 4,637,061). As to claim 1 Riese discloses a package 11 comprising: an enclosure; a first substance 57 within said enclosure; a second substance 61 within said enclosure; and a plastic zipper 23 segregating said first substance from said second substance, wherein opening

said plastic zipper allows mixing of said first substance with said second substance inside said enclosure, see figures 7 and 8.

As to claims 2, the container 11 is "gas permeable" in as much as is claimed as the container is said to be capable of gas sterilization by causing a sterilizing gas, such as ethylene oxide, to pass through the wall of the container, see col. 5, lines 19-24.

As to claims 5 and 6, said enclosure is formed of a first layer and a second layer. Where the first and second layers each include a perimeter, the perimeter being sealed to said perimeter to form said enclosure, see figure 1.

As to claims 7 and 8, equivalent pull tabs 29 are attached to an outer surface adjacent the zipper.

6. Claims 1, 2 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Showa Highpolymer Co. LTD. (Japanese document. 2000161053). As to claim 1 Showa discloses a package B comprising: an enclosure; a first substance within said enclosure; a second substance within said enclosure; and a plastic zipper A segregating said first substance from said second substance, wherein opening said plastic zipper allows mixing of said first substance with said second substance inside said enclosure, see the Abstract and PCT/US2004/013181 Written Opinon.

As to claims 5 and 6, said enclosure is formed of a first layer and a second layer. Where the first and second layers each include a perimeter, the perimeter being sealed to said perimeter to form said enclosure, see figure 1.

As to claims 7 and 8, equivalent pull tabs 7 are attached to an outer surface adjacent the zipper in figure 4.

7. Claims 1-9, 12, 16, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Detrie et al (Patent no. 2,916,197). As to claim 1 Detrie et al discloses a package 34 comprising: an enclosure; a first substance within said enclosure; a second substance within said enclosure; and a plastic zipper 48, 49 segregating said first substance from said second substance, wherein

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opening said plastic zipper allows mixing of said first substance with said second substance inside said enclosure, see col. Lines 20-30.

As to claims 2 and 12, the container 11 is "gas permeable" in as much as is claimed where the container is disclosed to be made of Polyethylene or cellophane. Prior evidence in 5 above demonstrates this material is manifestly gas permeable

As to claims 3 and 12, mixing of solid substances is contemplated in col. 1, lines 24 and 25.

As to claim 4, cellophane is manifestly transparent. As defined by dictionary.com Cellophane "a thin, flexible, transparent cellulose material made from wood pulp and used as a moistureproof wrapping".

As to claims 5 and 6, said enclosure is formed of a first layer and a second layer. Where the first and second layers each include a perimeter, the perimeter being sealed to said perimeter to form said enclosure, see figure 6.

As to claims 7, 8 and 17, equivalent pull tabs 33 are attached to an outer surface adjacent the zipper.

As to claim 9, equal size compartments are contemplated in col. 5, line 3.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 12, 14, 15, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Detrie et al (Patent no. 2,916,197). The difference between the claimed subject matter and Detrie et al resides in the mixing of the solid

substances producing a gas. Since the examiner can not determine whether or not the reference product inherently possesses properties which anticipate or render obvious the claimed product the rejection has basis for shifting the burden of proof to applicant as in *In re Fitzgerald et al*, 205 USPQ 594, see MPEP § 2112- 2112.02.

As to claims 14 and 33, the substances place within the package is considered a *prima facie* matter of design choice, within the level of ordinary skill, as the particular material is dependent upon what one desires to mix.

10. Claims 2, 3, 12-15 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Detrie et al* (Patent no. 2,916,197) in view of *Renner* (document WO 95/053237). The difference between the claimed subject matter and *Detrie et al* resides in the mixing of the solid substances producing a gas. It is stated in the PCT/US2004/013181 Written Opinion that *Renner* teaches the use of gas permeable enclosure having apertures, in the form of vents, to permit gases produced by the chemical reaction during mixing to escape.

Therefore, it is fairly taught and would have been obvious to one of ordinary skill in the art to modify the package of *Detrie et al* by constructing the package gas permeable as suggested by *Renner*, in order to permit escape of volatile pressure built up during mixing.

As to the mixing of a solid and solid substance or the particular materials mixed, it is considered a matter of design choice for the reason that the particularly claims 14 and 33, the substances place within the package is considered a *prima facie* matter of design choice, within the level of ordinary skill, as the particular material is dependent upon what one desires to mix

11. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Renner* (document WO 95/053237). The difference between the claimed subject matter and *Renner* resides in the mixing of the solid substances producing a gas. It is stated in the PCT/US2004/013181 Written Opinion that *Renner* teaches the use of gas permeable enclosure having apertures, in the form of vents, to permit gases produced by the chemical reaction during mixing to escape. It would have been obvious to one of ordinary skill in the art to place any substances desired to be mixed in the package of *Renner*, for the reason that particular substance

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is considered a matter of design choice, within the level of ordinary skill, dependent upon what one desires to mix.

12. Claims 1-9, 12-17 and 31-34, are rejected under 35 U.S.C. 103(a) as being unpatentable over Renner (document WO 95/053237) as applied to claims 12-15 above, and further in view of Riese (Patent no. 4,637,061). The difference between the claimed subject matter and Renner resides in the particular mechanism used to separate the components to be mixed.

Riese (Patent no. 4,637,061) teaches that it is known to one skilled in the art to employ a zipper with attached separation tabs as a means for separating components to be mixed. Accordingly, to employ a zipper segregating the substances to be mixed would have been an inventive modification but obvious to one of ordinary skill in the art, in order provide an easily actuated mechanism for opening the compartmented substances to be mixed.

As to claims 3, 14 and 33, it would have been obvious to one of ordinary skill in the art to place any substances desired to be mixed in the package of Renner, for the reason that particular substance is considered a matter of design choice, within the level of ordinary skill, dependent upon what one desires to mix.

13. Claims 10, 11 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over the prior art as applied to claims 1 and 32 above, and further in view of Spector (Patent no. 4,277,024). The difference between these claims and prior art resides in the package comprising an adhesive obscured by a cover. Spector discloses a package including an adhesive 15 exposed by peel off cover sheet 16. It would have been obvious to one of ordinary skill in the art to modify the prior art packages by constructing an adhesive exposed by peel off cover sheet as taught by Spector, in order to facilitate attachment of the package to a diverse or source, or surface, for storage.

REPLY BY APPLICANT OR PATENT OWNER TO THIS OFFICE ACTION

14. “In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to every ground of objection and rejection in this Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. The applicant’s or patent owner’s reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section. The reply must be reduced to writing (emphasis added)”, see 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

Pointing out specific distinctions means clearly indicating in the written response what features/elements or distinctions have been added to the claim/claims, where support is found in the specification for such recitations and how these features are not shown, taught, obvious or inherent in the prior art.

If no amendments are made to claims as applicant or patent owner believes the claims are patentable without further modification, the reply must distinctly and specifically point out the supposed errors in the examiner’s action and must respond to every ground of objection and rejection in the prior Office Action in the same vain as given above, 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

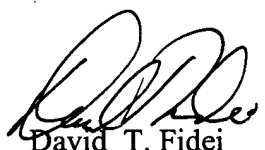
The examiner also points out, due to the change in practice as affecting final rejections, older decisions on questions of prematureness of final rejection or admission of subsequent amendments do not necessarily reflect present practice. “Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)” (emphasis mine), see MPEP 706.07(a).

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Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fidei whose telephone number is (571) 272-4553. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David T. Fidei
Primary Examiner
Art Unit 3728

dtf
October 29, 2005